UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,308	09/16/2003	Robert Sutherland	005513P017	4329

7590 10/08/2008

Daniel E. Ovanezian
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
Seventh Floor
12400 Wilshire Boulevard
Los Angeles, CA 90025-1026

EXAMINER	
CHAO, ELMER M	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,308	SUTHERLAND ET AL.	
	Examiner	Art Unit	
	ELMER CHAO	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-21,24,31-43 and 53-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,24,31-43, and 53-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 9/10/2008.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 9/28/2008 was filed after the mailing date of the Advisory Action on 9/17/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

4. Applicant's arguments filed 9/10/2008 have been fully considered but they are not persuasive.

5. Regarding Applicants' arguments with respect to claims 31, 32, 35, and 36, Applicants argue that Holupka et al. do not teach monitoring in vivo at least one

physiological parameter of the body. However, Examiner asserts that Holupka et al. that the term 'physiological parameter' is very broad and can encompass a wide range of parameters. At the very least Holupka et al. teach monitoring the location of prostate relative to a landmark (see abstract), which is considered a physiological parameter.

6. Regarding Applicants' arguments with respect to claim 15, Applicants argue that Grzeszczuk et al. do not teach an internal coordinate system being based on the markers other than the sensors. However, Examiner asserts that the rejection states that the sensor would be obvious to use as the medical instrument which is being tracked. Therefore, the markers and sensor do not overlap in function. Furthermore, Examiner has included an additional reference for the rejection of claims 15-21, 24, and 43. Examiner has also included an additional grounds of rejection for claim 15.

7. Regarding Applicants' arguments with respect to claim 18, Examiner has included an additional reference to support the rejection.

8. Regarding Applicants' arguments with respect to claim 21, Applicants argue that Grzeszczuk et al. do not teach the tracking of the position of the sensor device over time and as the body moves. Examiner disagrees and asserts that Grzeszczuk et al. do teach tracking the position of the sensor device as the body moves. Since the tool is tracked, it would involve being tracked over the course of time by definition. Examiner informs that a living human body always contains internal movement and would satisfy the latter part of the limitation.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 15, 31, 32, 35, 36, and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by Holupka et al. (U.S. 5,810,007).

Regarding **claims 31, 32, 35, and 36,** Holupka et al. teach a method of imaging a plurality of markers and an in vivo landmark (prostate gland) in a first imaging modality CT (abstract; col. 3, lines 53-64; col. 4, lines 13-15, and figures 2 & 3); correlating a position of the in vivo landmark relative to at least one of the plurality of markers (col. 3, lines 61-67; fig. 2); imaging the plurality of markers in a second modality (col. 3, line 62), wherein the in vivo landmark is not imageable in the second modality (col. 1, lines 54-56); and determining the position of the in vivo landmark relative to at least one of the plurality of markers based on the correlating (col. 3, lines 61-67).

Specifically regarding claim 31, the actual landmark is not imaged by the x-ray (col. 1, lines 54-56). Thus, the markers are imaged by both modalities but the landmark is not. Therefore, it doesn't matter which imaging modality is labeled as "first" or "second" because the limitations are satisfied either way with one modality being able to image the landmark and one modality not being able to image the landmark.

Regarding **claims 15 and 54,** Holupka et al. teach the limitations as discussed above, including a sensor with markers (see abstract, refer to ultrasound probe and

fiducials). The markers are not the sensor itself since the sensor can be considered the portion of the ultrasound probe not acting as the fiducials.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Alternatively **claim 15, and claims 16-21, 24, 43, 53, 59, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Grzeszczuk et al. (U.S.2002/0077543 A1) in view of Scarantino et al. (U.S. 6,402,689 B1).

Regarding **claims 15, 16, 21, 24, 53, 59, and 60,** Grzeszczuk et al. teach a method comprising: situating a device in a body (para [0056], refer to surgical tools); and identifying a position of the device relative to an internal coordinate system using an imaging technique (para [0056], refer to 'registration'), wherein the internal coordinate system is based on a plurality of markers located in the body having an imageable marker property (para [0052] & para [0056]), wherein identifying comprises identifying the position relative to the at least one of the plurality of markers (para [0053]); and tracking the device over time (abstract)

Grzeszczuk et al. teach the limitations as discussed above. Grzeszczuk et al. also teach the device being tracked to be a medical instrument inside of a patient (abstract). Grzeszczuk et al. fail to explicitly teach the medical instrument being a

sensor device. However, Scarantino et al. teach a medical instrument that is a radiation sensor device (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Grzeszczuk et al. to teach the medical tool to be a radiation sensor device in order to quantify the amount of radiation received at a tumor (for motivation see abstract).

Regarding **claim 18**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach the sensor device having a length less than approximately 26 millimeters. However, Scarantino et al. teach implantable devices that have reduced size (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use a very small implantable device in order to implant it with a needle (for motivation see col. 21, lines 31-33).

Regarding **claim 19**, Grzeszczuk et al. teach identifying the position relative to an anatomical landmark (para [0052], refer to "skeletal landmark").

Regarding **claim 20**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach identifying the position of the device relative to an organ. However, Grzeszczuk et al. do teach using anatomical landmarks for image registration. These landmarks would then show up on the display while the medical instrument is being tracked. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use certain organs as landmarks as a matter of design choice since different medical procedures would involve different in vivo locations which may cause certain organs with better visibility and proximity to be used for registration purposes.

Regarding **claims 17, and 43**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach implanting the sensor through injection. However, the methods of implanting a medical sensor will vary based on the type of sensor and the location at which the procedure is performed. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Grzeszczuk et al. to include injecting the sensor as a matter of design choice since the instant application also lacks any mention of a specific advantage of implanting a sensor via injection methods (for example see para [0040] in the Specifications of the instant application). Furthermore, Scarantino et al. teach implanting a device through injection (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method to include injection through a needle in order to minimize invasiveness.

13. **Claims 33, 34, and 37-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka et al.

Regarding **claims 33 and 34**, Holupka et al. teach that the in vivo landmark is a sensor device (col. 3, lines 50-55; fig. 2) and comprises at least one of the plurality of markers (col. 3, lines 61-67; fig. 2).

Regarding **claims 37, 38, 40, and 41**, Holupka et al. teach a second imaging modality except for the modality of being kV imaging or MV imaging. It is well known in the art that kV imaging and MV imaging provide quality images and excellent localization. It would have been obvious to a person of skill in the art at the time of the

invention to use kV imaging or MV imaging as the second imaging modality to achieve quality images with excellent target localization.

Regarding **claim 39**, Holupka et al. teach a first imaging modality except for the modality being MRI. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using magnetic resonance imaging for the first imaging modality to achieve quality images with excellent target localization.

Regarding **claim 42**, Holupka et al. teach a second imaging modality except for the modality being ultrasound when the first imaging modality is magnetic resonance imaging. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using these imaging techniques in the manner provide high quality images and excellent localization.

14. **Claims 55-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka et al. in view of Scarantino et al.

Regarding **claim 55**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach sensing a radiation dose. However, Scarantino et al. teach sensing a radiation dose (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Holupka et al. to include sensing radiation order to quantify the actual amount of radiation received at a tumor (for motivation see abstract).

Regarding **claim 56**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach sensing the temperature of the body. However, Scarantino et al. teach sensing temperature during radiation therapy (col. 11, lines 1-4). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Holupka et al. to including sensing temperature in order to determine penetration depth (for motivation see col. 11, lines 1-4).

Regarding **claims 57 and 58**, Holupka et al. teach the limitations as discussed above but fail to explicitly teach implanting the sensor through injection. However, the methods of implanting a medical sensor will vary based on the type of sensor and the location at which the procedure is performed. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Holupka et al. to include injecting the sensor as a matter of design choice since the instant application also lacks any mention of a specific advantage of implanting a sensor via injection methods (for example see para [0040] in the Specifications of the instant application). Furthermore, Scarantino et al. teach implanting a device through injection (col. 21, lines 31-33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method to include injection through a needle in order to minimize invasiveness.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/E. C./
Examiner, Art Unit 3737
10/1/2008